```
=> immunization
L7        87180 IMMUNIZATION

=> L1 and L7
L8           19 L1 AND L7

=> HIV and L8
L9            0 HIV AND L8

=> HSV and L8
L10           0 HSV AND L8

=> papilloma and L8
L11           0 PAPILLOMA AND L8

=> candida and L8
L12           0 CANDIDA AND L8

=> HBV and L8
L13           0 HBV AND L8

=> treponema and L8
L14           0 TREPONEMA AND L8

=> gonoccal and L8
L15           0 GONOCCAL AND L8

=> chlamydia and L8
L16           0 CHLAMYDIA AND L8

=> D L8 IBIB TI SO AU ABS 1-19
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L8 ANSWER 12 OF 19 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN
ACCESSION NUMBER: 2001:387359 BIOSIS
DOCUMENT NUMBER: PREV200100387359
TITLE: Hepatitis B vaccine in infants: A randomized controlled trial comparing gluteal versus anterolateral thigh muscle administration.
AUTHOR(S): Alves, Andrea Santos Rafael; Nascimento, Cristiane M. R.; Granato, Celso H.; Sato, Helena Keiko; Morgato, Marina F.; Pannuti, Claudio S. [Reprint author]
CORPORATE SOURCE: Av. Dr. Eneas de Carvalho Aguiar 470, 05403-000, Sao Paulo, SP, Brazil
cpannuti@usp.br
SOURCE: Revista do Instituto de Medicina Tropical de Sao Paulo, (May-June, 2001) Vol. 43, No. 3, pp. 139-143. print.
CODEN: RMTSAE. ISSN: 0036-4665.
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 15 Aug 2001
Last Updated on STN: 19 Feb 2002

TI Hepatitis B vaccine in infants: A randomized controlled trial comparing gluteal versus anterolateral thigh muscle administration.

SO Revista do Instituto de Medicina Tropical de Sao Paulo, (May-June, 2001) Vol. 43, No. 3, pp. 139-143. print.
CODEN: RMTSAE. ISSN: 0036-4665.

AU Alves, Andrea Santos Rafael; Nascimento, Cristiane M. R.; Granato, Celso H.; Sato, Helena Keiko; Morgato, Marina F.; Pannuti, Claudio S. [Reprint author]

AB A significantly diminished antibody response to hepatitis B vaccine has been demonstrated in adults when the buttock is used as the **injection** site. However, in Brazil, the buttock continues to be recommended as site of **injection** for intramuscular administration of vaccines in infants. In this age group, there are no controlled studies evaluating the immunogenicity of the hepatitis B vaccine when administered at this site. In the present study, 258 infants were randomized to receive the hepatitis B vaccine either in the buttock (n = 123) or in the anterolateral **thigh** muscle (n = 135). The **immunization** schedule consisted of three doses of hepatitis B vaccine (Engerix B(R), 10 mug) at 2, 4 and 9 months of age. There were no significant differences in the proportion of seroconversion (99.3% X 99.2%), or in the geometric mean titer of ELISA anti-HBs (1,862.1 X 1,229.0 mIU/mL) between the two groups. This study demonstrates that a satisfactory serological response can be obtained when the hepatitis B vaccine is administered intramuscularly into the buttock.

L8 ANSWER 11 OF 19 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN
ACCESSION NUMBER: 2002:612530 BIOSIS
DOCUMENT NUMBER: PREV200200612530
TITLE: Safety and immunogenicity of pneumococcal conjugate vaccine in combination with diphtheria, tetanus toxoid, pertussis and Haemophilus influenzae type b conjugate vaccine.
AUTHOR(S): Obaro, Stephen K. [Reprint author]; Enwere, Godwin C.; Deloria, Maria; Jaffar, Shabbar; Goldblatt, David; Brainsby, Kate; Hallander, Hans; Mcinnes, Pamela; Greenwood, Brian M.; McAdam, Keith P. W. J.
CORPORATE SOURCE: Imperial College School of Medicine, London, UK
SOURCE: Pediatric Infectious Disease Journal, (October, 2002) Vol. 21, No. 10, pp. 940-946. print.
ISSN: 0891-3668.
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 27 Nov 2002
Last Updated on STN: 27 Nov 2002

TI Safety and immunogenicity of pneumococcal conjugate vaccine in combination with diphtheria, tetanus toxoid, pertussis and Haemophilus influenzae type b conjugate vaccine.

SO Pediatric Infectious Disease Journal, (October, 2002) Vol. 21, No. 10, pp. 940-946. print.
ISSN: 0891-3668.

AU Obaro, Stephen K. [Reprint author]; Enwere, Godwin C.; Deloria, Maria; Jaffar, Shabbar; Goldblatt, David; Brainsby, Kate; Hallander, Hans; Mcinnes, Pamela; Greenwood, Brian M.; McAdam, Keith P. W. J.

AB Background: Pneumococcal polysaccharide/protein conjugate vaccines (PnCV) are immunogenic and effective in infancy. However, an addition to the nine currently recommended vaccine **injections** during the first year of life of African children may be a deterrent to participation in a PnCV program. Thus we have evaluated the safety and immunogenicity of a 9-valent PnCV (Wyeth Lederle Pediatrics and Vaccines) mixed with diphtheria, tetanus toxoid, cell pertussis and Haemophilus influenzae type b (TETRAMUNE). Methods: Healthy Gambian infants were randomized at the age of 2 months to receive three doses 1 month apart of either (1) placebo reconstituted in TETRAMUNE in the right **thigh** (control) or (2) PnCV in the left **thigh** and TETRAMUNE in the right **thigh** (separate) or (3) PnCV reconstituted in TETRAMUNE as a single **injection** in the right **thigh** (combined). The vaccines were given together with routine Expanded Program on **Immunization** vaccines. Adverse reactions were recorded after vaccination, and antibody concentrations were measured by enzyme-linked immunosorbent assays. Results: Local induration and tenderness were observed more commonly at the site of **injection** of TETRAMUNE than at the site of **injection** with PnCV after each dose of vaccination. Swelling at the site of **injection** was encountered more frequently at the site of administration of TETRAMUNE than at the site of administration PnCV ($P<0.00001$ for Doses 1 and 2 and $P<0.0009$ for Dose 3). Swelling at the site of administration of TETRAMUNE mixed with PnCV was comparable with that observed for TETRAMUNE alone. Although most mothers reported that the babies "felt hot" 24 h after each **injection**, febrile reactions (temperature, gtoreq38degreeC) were infrequent and resolved with antipyretics. Geometric mean titer for anti-polyribosylribitol phosphate antibody was 11.6 mug/ml (95% confidence limits (95% CI), 9.2, 14.6) in the control group and comparable with 13.3 mug/ml (95% CI 11.0, 16.0) in the combined group and significantly higher at 17.9 mug/ml (95% CI 14.7, 21.9; $P=0.01$) in the separate group. Geometric mean concentrations of serotype-specific pneumococcal antibodies were higher in the combined group than the separate group for all nine serotypes. Antibody responses to diphtheria and pertussis antigens were similar in all groups. Anti-tetanus toxoid antibody concentrations were lowest in the combined group (6.66 IU/ml, 95% CI 5.77, 7.68 in the control group; 5.15 IU/ml, 95% CI 4.39, 6.03 in the combined group; $P=0.02$). However, all vaccinees

achieved protective antibody values. Conclusion: The combination of TETRAMUNE and PnCV is safe and immunogenic.

L6 ANSWER 16 OF 18 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN
ACCESSION NUMBER: 1989:341768 BIOSIS
DOCUMENT NUMBER: PREV198988044768; BA88:44768
TITLE: ADVERSE REACTIONS TO DIPHTHERIA TETANUS PERTUSSIS-POLIO **VACCINATION** AT 18 MONTHS OF AGE EFFECT OF INJECTION SITE AND NEEDLE LENGTH.
AUTHOR(S): IPP M M [Reprint author]; GOLD R; GOLDBACH M; MARESKY D C; SAUNDERS N; GREENBERG S; DAVY T
CORPORATE SOURCE: DEP PEDIATRICS, UNIV TORONTO, HOSP SICK CHILDREN, 555 UNIVERSITY AVENUE, TORONTO, ONTARIO, CANADA M5G 1X8
SOURCE: Pediatrics, (1989) Vol. 83, No. 5, pp. 679-682.
CODEN: PEDIAU. ISSN: 0031-4005.
DOCUMENT TYPE: Article
FILE SEGMENT: BA
LANGUAGE: ENGLISH
ENTRY DATE: Entered STN: 20 Jul 1989
Last Updated on STN: 20 Jul 1989

TI ADVERSE REACTIONS TO DIPHTHERIA TETANUS PERTUSSIS-POLIO **VACCINATION** AT 18 MONTHS OF AGE EFFECT OF INJECTION SITE AND NEEDLE LENGTH.

SO Pediatrics, (1989) Vol. 83, No. 5, pp. 679-682.
CODEN: PEDIAU. ISSN: 0031-4005.

AU IPP M M [Reprint author]; GOLD R; GOLDBACH M; MARESKY D C; SAUNDERS N; GREENBERG S; DAVY T

AB Adverse reactions after diphtheria, pertussis, tetanus, polio **vaccination** at 18 months of age were investigated in three groups: 74 children injected in the deltoid muscle with a 16-mm (5/8-in) needle, 64 in the anterolateral **thigh** with a 16-mm needle, and 67 in the anterolateral **thigh** with a 25-mm (1-in) needle. No significant differences in systemic reactions were observed. Severe pain occurred in 30.5% of the groups injected in the **thigh** compared with only 8.1% of the group injected in the arm ($P < .001$). Children vaccinated in the **thigh** had decreased movement of the extremity significantly more often than those injected in the arm (49.9% v 25.6%, $P < .005$), and two thirds of the former limped for 24 to 48 hours. Redness and swelling were observed more often after **injection** in the arm than in the **thigh** (58.1% v 26.7%, $P < .0005$). The only effect of changing needle length in the groups injected in the **thigh** was the occurrence of more redness and swelling in children vaccinated with the 16-mm needle compared with the 25-mm needle. Overall, parents rated more reactions as moderate to severe among children injected in the **thigh** than among children injected in the arm (64.2% v 37.9%, $P < .001$). The deltoid muscle appears to be the preferred site for administration of diphteria, petussis, tetanus, polio vaccine at 18 months of age

L6 ANSWER 12 OF 18 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN
ACCESSION NUMBER: 1997:43522 BIOSIS
DOCUMENT NUMBER: PREV199799335510
TITLE: Randomised trial of the effect of co-administration with acellular pertussis DTP vaccine on immunogenicity of Haemophilus influenzae type b conjugate vaccine.
AUTHOR(S): Eskola, Juhani [Reprint author]; Olander, Rose-Marie; Hovi, Tapani; Litmanen, Leila; Peltola, Sara; Kayhty, Helena
CORPORATE SOURCE: National Public Health Inst., 00300 Helsinki, Finland
SOURCE: Lancet (North American Edition), (1996) Vol. 348, No. 9043, pp. 1688-1692.
ISSN: 0099-5355.
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 28 Jan 1997
Last Updated on STN: 28 Jan 1997

TI Randomised trial of the effect of co-administration with acellular pertussis DTP vaccine on immunogenicity of Haemophilus influenzae type b conjugate vaccine.

SO Lancet (North American Edition), (1996) Vol. 348, No. 9043, pp. 1688-1692. ISSN: 0099-5355.

AU Eskola, Juhani [Reprint author]; Olander, Rose-Marie; Hovi, Tapani; Litmanen, Leila; Peltola, Sara; Kayhty, Helena

AB Background: Inclusion of new vaccines in **vaccination** programmes for children would be easier if they could be combined with existing vaccines. Vaccines containing acellular pertussis in the diphtheria/tetanus/pertussis (DTP-a) combination are expected to replace the conventional whole-cell vaccines (DTP-w). We tested the immunogenicity and safety of a combination of DTP-a with the Haemophilus influenzae type b (Hib) conjugate of Hib capsular polysaccharide and tetanus toxid (PRP-T), and inactivated poliovirus vaccine (IPV). Methods: 120 infants were enrolled and randomised to four groups to receive DTP-a at ages 2, 4, and 6 months. At 4 and 6 months they also received Hib conjugate and IPV, either as separate **injections** or mixed with DTP-a. All **injections** were given intramuscularly in the anterolateral area of the **thigh**. Any reactions after each **vaccination** were noted by the parents. EIA was used to measure titres of diphtheria, tetanus, and pertussis antibodies, RIA for Hib anticapsular antibodies, and microneutralisation assay for poliovirus antibodies from serum samples collected at the ages of 2, 4, 6, and 7 months. Findings: There were 30 infants in each group. Only mild adverse events were reported. There was a tendency towards slightly lower concentrations of filamentous haemagglutinin, tetanus, and poliovirus 1 antibodies when the vaccines were mixed. However, there was a more pronounced difference (p=4 times 10-8) in Hib antibodies between groups receiving Hib capsular polysaccharide mixed with DTP-a (geometric mean concentrations 0.37 mu-g/mL and 0.56 mu-g/mL) compared with groups receiving the vaccines separately (3.10 mu-g/mL and 3.94 mu-g/mL). Interpretation: Administration of premixed DTP-a, Hib conjugate, and IPV affect the immune response significantly. The mechanism of this interference is not clear. The immunogenicity of all antigens must be tested before new combinations can be accepted for **vaccination** programmes for infants.

L6 ANSWER 10 OF 18 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN
ACCESSION NUMBER: 1999:398314 BIOSIS
DOCUMENT NUMBER: PREV199900398314
TITLE: Information to be provided to parents of children to be vaccinated with diphtheria-tetanus-pertussis acellular vaccine.
AUTHOR(S): Tozzi, A. E. [Reprint author]; Ciofi degli Atti, M. L.; Salmaso, S.; Anemona, A.; Parroccini, S.
CORPORATE SOURCE: Laboratorio di Epidemiologia e Biostatistica, Istituto Superiore di Sanita, Reparto Malattie Infettive, V.le Regina Elena, 299, 00161, Roma, Italy
SOURCE: Igiene Moderna, (April, 1999) Vol. 111, No. 4, pp. 391-400. print.
CODEN: IGMPAX. ISSN: 0019-1655.
DOCUMENT TYPE: Article
LANGUAGE: Italian
ENTRY DATE: Entered STN: 8 Oct 1999
Last Updated on STN: 8 Oct 1999

TI Information to be provided to parents of children to be vaccinated with diphtheria-tetanus-pertussis acellular vaccine.

SO Igiene Moderna, (April, 1999) Vol. 111, No. 4, pp. 391-400. print.
CODEN: IGMPAX. ISSN: 0019-1655.

AU Tozzi, A. E. [Reprint author]; Ciofi degli Atti, M. L.; Salmaso, S.; Anemona, A.; Parroccini, S.

AB The data provided by the Progetto Pertosse, a study on 15,601 children immunized with whole-cell or acellular diphtheria-tetanus-pertussis vaccines, or with a diphtheria-tetanus vaccine, allowed to gather detailed information on adverse reactions which can occur after the administration of the acellular vaccines used in Italy. Families of pertussis vaccinees should be informed in detail of expected adverse reactions. The results from Progetto Pertosse show that the reactogenicity of acellular vaccines is much lower than that observed with whole-cell vaccines, and similar to diphtheria-tetanus vaccines. The most common adverse events such as fever and local reactions start and end in most cases within 2 days of administration, and in the majority of cases have a short duration. The simultaneous administration of polio and hepatitis B vaccines does not increase the reactogenicity and does not affect the efficacy of acellular vaccines. **Injection** in the buttock is associated with a lower probability of observing common adverse reactions when compared to **injection** in the **thigh**. Children who experienced an adverse reaction are more likely to present the same event at following doses. Appropriate information to parents of vaccinees on the safety of acellular pertussis vaccines is necessary, it is useful to reassure the families of vaccinees and avoid interruptions of the immunization series due to false contraindications.

L6 ANSWER 8 OF 18 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN
ACCESSION NUMBER: 2001:386015 BIOSIS
DOCUMENT NUMBER: PREV200100386015
TITLE: Reactogenicity of DTPa-HBV/Hib vaccine administered as a single injection vs DTPa-HBV and Hib vaccines administered simultaneously at separate sites, to infants at 2, 4 and 6 months of age.
AUTHOR(S): Omenaca, F.; Dal-Re, R. [Reprint author]; D'Apuzzo, V.; Kattamis, C.; Gnehm, H. P.; Garcia-Sicilia, J.; Garcia-Corbeira, P.
CORPORATE SOURCE: Medical Department, SmithKline Beecham Pharmaceuticals, c/Dr Severo Ochoa 2, 28760 Tres Cantos, Madrid, Spain rafael.dal-re@gsk.com
SOURCE: Vaccine, (20 July, 2001) Vol. 19, No. 30, pp. 4260-4266. print.
CODEN: VACCDE. ISSN: 0264-410X.
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 15 Aug 2001
Last Updated on STN: 19 Feb 2002

TI Reactogenicity of DTPa-HBV/Hib vaccine administered as a single injection vs DTPa-HBV and Hib vaccines administered simultaneously at separate sites, to infants at 2, 4 and 6 months of age.

SO Vaccine, (20 July, 2001) Vol. 19, No. 30, pp. 4260-4266. print.
CODEN: VACCDE. ISSN: 0264-410X.

AU Omenaca, F.; Dal-Re, R. [Reprint author]; D'Apuzzo, V.; Kattamis, C.; Gnehm, H. P.; Garcia-Sicilia, J.; Garcia-Corbeira, P.

AB An open, randomised, multicentre trial was performed to assess the reactogenicity and safety profile of the administration of a candidate Haemophilus influenzae type b (Hib) conjugate vaccine with a quadrivalent diphtheria-tetanus-acellular pertussis-hepatitis B (DTPa-HBV) vaccine as a single **injection** (Group 1) versus the simultaneous administration of the latter vaccine (DTPa-HBV) and an available Hib conjugate vaccine (Group 2) in opposite **thighs**, as a primary **vaccination** course to healthy infants at 2, 4 and 6 months of age. Eight hundred and eighty five infants (9.3+-1.4 weeks old) were randomly allocated to Group 1 (n=665) and Group 2 (n=221). Oral polio vaccine was given concomitantly to all subjects. Blood samples (pre-**vaccination** and 1 month after the third dose) were obtained from a subset of infants (Group 1, 73; Group 2, 22) for serological determinations. Local and general symptoms were recorded by parents on diary cards. 2614 diary cards (Group 1, 1966; Group 2, 648) were collected. There were no statistically significant differences in the incidence of local and general symptoms between groups. Pain such that the infant cried when limb was moved was reported in 0.6 and 0.2% in groups 1 and 2, respectively. Redness and swelling (>20 mm in diameter) were recorded between 2.1 and 3% in both groups. Fussiness preventing normal activities was the most frequently reported general symptom in both groups (1.6 and 1.9% in groups 1 and 2, respectively). Fever (rectal temperature >39.5degreeC) was reported in 0.4% (Group 1) and 0.3% (Group 2). All subjects included in the immunogenicity analysis had seroprotective or seropositive titres to the diphtheria, tetanus, hepatitis B and pertussis components of the vaccines. About 99 and 100% of infants had anti-PRP titres gtoreq0.15 mcg/ml in groups 1 and 2, respectively. This study indicates that DTPa-HBV vaccine given in a single **injection** with a candidate Hib conjugate vaccine has a similar reactogenicity profile to that of two commercially available vaccines (DTPa-HBV, Hib) given in two simultaneous **injections** to infants 2, 4 and 6 months of age.

L6 ANSWER 4 OF 18 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN
ACCESSION NUMBER: 2003:457990 BIOSIS
DOCUMENT NUMBER: PREV200300457990
TITLE: Comparison of the reactogenicity and immunogenicity of a combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated polio (DTPa-HBV-IPV) vaccine, mixed with the Haemophilus influenzae type b (Hib) conjugate vaccine and administered as a single injection, with the DTPa-IPV/Hib and hepatitis B vaccines administered in two simultaneous injections to infants at 2, 4 and 6 months of age.
AUTHOR(S): Aristegui, J.; Dal-Re, R.; Diez-Delgado, J.; Mares, J.; Casanovas, J. M.; Garcia-Corbeira, P. [Reprint Author]; De Frutos, E.; Van Esso, D.; Verdaguer, J.; de la Flor, J.; Moraga, F.; Boceta, R.; Garcia-Martinez, J. A.
CORPORATE SOURCE: Medical Department, GlaxoSmithKline, c/Severo Ochoa 2, Tres Cantos, PTM, 28760, Madrid, Spain
pilar.garcia-corbeira@gsk.com
SOURCE: Vaccine, (8 September 2003) Vol. 21, No. 25-26, pp. 3593-3600. print.
ISSN: 0264-410X (ISSN print).
DOCUMENT TYPE: Article
LANGUAGE: English
ENTRY DATE: Entered STN: 8 Oct 2003
Last Updated on STN: 8 Oct 2003

TI Comparison of the reactogenicity and immunogenicity of a combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated polio (DTPa-HBV-IPV) vaccine, mixed with the Haemophilus influenzae type b (Hib) conjugate vaccine and administered as a single injection, with the DTPa-IPV/Hib and hepatitis B vaccines administered in two simultaneous injections to infants at 2, 4 and 6 months of age.

SO Vaccine, (8 September 2003) Vol. 21, No. 25-26, pp. 3593-3600. print.
ISSN: 0264-410X (ISSN print).

AU Aristegui, J.; Dal-Re, R.; Diez-Delgado, J.; Mares, J.; Casanovas, J. M.; Garcia-Corbeira, P. [Reprint Author]; De Frutos, E.; Van Esso, D.; Verdaguer, J.; de la Flor, J.; Moraga, F.; Boceta, R.; Garcia-Martinez, J. A.

AB An open, randomised, multicentre trial was performed to compare the reactogenicity and safety profile of the administration of a hexavalent diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated polio (DTPa-HBV-IPV) vaccine administered in one **injection** mixed with Haemophilus influenzae type b (Hib) conjugate vaccine (Group 1) with that of a pentavalent DTPa-IPV vaccine mixed with a Hib vaccine (DTPa-IPV/Hib), simultaneously administered with HBV (Group 2) in two **injections** in opposite **thighs**, as a primary **vaccination** course, to healthy infants at 2, 4 and 6 months of age. A total of 235 completed the study, 120 from Group 1 and 115 from Group 2. Blood samples (pre-**vaccination** and 1 month after the third dose) were obtained from a subset of infants (Group 1: 40; Group 2: 31) to assess the immune response to **vaccination**. Local and general solicited symptoms were recorded by parents on diary cards. Seven hundred and five diary cards (Group 1: 360; Group 2: 345) were collected. The clinically relevant and most commonly reported local reaction was pain (infant cried when the limb was moved) in 2.5% (Group 1) and 1.2% (Group 2) of diary cards. Fever was more frequently reported in Group 1 (21% of diary cards) than in Group 2 (12% of diary cards). However only 3 and 2% of doses in Groups 1 and 2, respectively, were responsible for a rectal temperature between 38.6 and 39.5 degreeC and only one case (Group 2) had gtoreq 39.5 degreeC. Other clinically relevant general symptoms were rarely recorded: irritability (2-2.8%), loss of appetite (0.3-0.6%) and drowsiness (0.3-0.3%). All subjects included in the immunogenicity analysis had seroprotective titres to diphtheria, tetanus, polio virus types 1 and 3, Hib. Almost all subjects were seroprotected for anti-polio type 2 and hepatitis B (with the exception of 1 subject in Group 1 for each antigen). The vaccines

response rates to pertussis antigens were over 97 and 90% in Groups 1 and 2, respectively. This study shows that, from a clinical perspective, the DTPa-HBV-IPV/Hib vaccine given in a single **injection** has a similar reactogenicity and safety profile to that of two licensed vaccines (DTPa-IPV/Hib, HBV) given in two simultaneous **injections** to infants at 2, 4 and 6 months of age. This is a valuable advantage, since in some countries, such as Spain and the UK, an additional **injection** (for the administration of meningococcal C conjugate vaccine) has been recently included in the infants' **vaccination** calendars.

L6 ANSWER 3 OF 18 CAPLUS COPYRIGHT 2004 ACS on STN
ACCESSION NUMBER: 1997:59715 CAPLUS
DOCUMENT NUMBER: 126:102765
TITLE: Randomized trial of the effect of co-administration with acellular pertussis DTP vaccine on immunogenicity of Haemophilus influenzae type b conjugate vaccine
AUTHOR(S): Eskola, Juhani; Olander, Rose-Marie; Hovi, Tapani; Litmanen, Leila; Peltola, Sara; Kayhty, Helena
CORPORATE SOURCE: National Public Health Institute, Helsinki, 00300, Finland
SOURCE: Lancet (1996), 348(9043), 1688-1692
CODEN: LANCAO; ISSN: 0140-6736
PUBLISHER: Lancet
DOCUMENT TYPE: Journal
LANGUAGE: English

TI Randomized trial of the effect of co-administration with acellular pertussis DTP vaccine on immunogenicity of Haemophilus influenzae type b conjugate vaccine

SO Lancet (1996), 348(9043), 1688-1692
CODEN: LANCAO; ISSN: 0140-6736

AU Eskola, Juhani; Olander, Rose-Marie; Hovi, Tapani; Litmanen, Leila; Peltola, Sara; Kayhty, Helena

AB Inclusion of new vaccines in **vaccination** programs for children would be easier if they could be combined with existing vaccines. Vaccines containing acellular pertussis in the diphtheria/tetanus/pertussis (DTP-a) combination are expected to replace the conventional whole-cell vaccines (DTP-w). We tested the immunogenicity and safety of a combination of DTP-a with the Haemophilus influenzae type b (Hib) conjugate of Hib capsular polysaccharide and tetanus toxoid (PRP-T), and inactivated poliovirus vaccine (IPV). Methods 120 infants were enrolled and randomized to four groups to receive DTP-a at ages 2, 4, and 6 mo. At 4 and 6 mo they also received Hib conjugate and IPV, either as sep. **injections** or mixed with DTP-a. All **injections** were given i.m. in the anterolateral area of the **thigh**. Any reactions after each **vaccination** were noted by the parents. EIA was used to measure titers of diphtheria, tetanus, and pertussis antibodies, RIA for Hib anticapsular antibodies, and microneutralization assay for poliovirus antibodies from serum samples collected at the ages of 2, 4, 6, and 7 mo. Findings There were 30 infants in each group. Only mild adverse events were reported. There was a tendency towards slightly lower concns. of filamentous hemagglutinin, tetanus, and poliovirus 1 antibodies when the vaccines were mixed. However, there was a more pronounced difference (p=4+10-8) in Hib antibodies between groups receiving Hib capsular polysaccharide mixed with DTP-a (geometric mean concns. 0Σ37 μg/mL and 0Σ56 μg/mL) compared with groups receiving the vaccines sep. (3Σ10 μg/mL and 3Σ94 μg/mL). Interpretation Administration of premixed DTP-a, Hib conjugate, and IPV affect the immune response significantly. The mechanism of this interference is not clear. The immunogenicity of all antigens must be tested before new combinations can be accepted for **vaccination** programs for infants.

L6 ANSWER 2 OF 18 CAPLUS COPYRIGHT 2004 ACS on STN
ACCESSION NUMBER: 2001:520223 CAPLUS
DOCUMENT NUMBER: 136:230830
TITLE: Reactogenicity of DTPa-HBV/Hib vaccine administered as a single injection vs DTPa-HBV and Hib vaccines administered simultaneously at separate sites, to infants at 2, 4 and 6 months of age
AUTHOR(S): Omenaca, F.; Dal-Re, R.; D'Apuzzo, V.; Kattamis, C.; Gnehm, H. P.; Garcia-Sicilia, J.; Garcia-Corbeira, P.
CORPORATE SOURCE: The European DTPa-HBV/Hib 041 Study Group, Departments of Neonatology and Paediatrics, La Paz Hospital, Madrid, Spain
SOURCE: Vaccine (2001), 19(30), 4260-4266
CODEN: VACCDE; ISSN: 0264-410X
PUBLISHER: Elsevier Science Ltd.
DOCUMENT TYPE: Journal
LANGUAGE: English
TI Reactogenicity of DTPa-HBV/Hib vaccine administered as a single injection vs DTPa-HBV and Hib vaccines administered simultaneously at separate sites, to infants at 2, 4 and 6 months of age
SO Vaccine (2001), 19(30), 4260-4266
CODEN: VACCDE; ISSN: 0264-410X
AU Omenaca, F.; Dal-Re, R.; D'Apuzzo, V.; Kattamis, C.; Gnehm, H. P.; Garcia-Sicilia, J.; Garcia-Corbeira, P.
AB An open, randomized, multicenter trial was performed to assess the reactogenicity and safety profile of the administration of a candidate Haemophilus influenzae type b (Hib) conjugate vaccine with a quadrivalent diphtheria-tetanus-acellular pertussis-hepatitis B (DTPa-HBV) vaccine as a single **injection** (Group 1) vs. the simultaneous administration of the latter vaccine (DTPa-HBV) and an available Hib conjugate vaccine (Group 2) in opposite **thighs**, as a primary **vaccination** course to healthy infants at 2, 4 and 6 mo of age. Eight hundred and eighty five infants (9.3±1.4 wk old) were randomly allocated to Group 1 (n=665) and Group 2 (n=221). Oral polio vaccine was given concomitantly to all subjects. Blood samples (pre-**vaccination** and 1 mo after the third dose) were obtained from a subset of infants (Group 1, 73; Group 2, 22) for serol. detns. Local and general symptoms were recorded by parents on diary cards. 2614 diary cards (Group 1, 1966; Group 2, 648) were collected. There were no statistically significant differences in the incidence of local and general symptoms between groups. Pain such that the infant cried when limb was moved was reported in 0.6 and 0.2% in groups 1 and 2, resp. Redness and swelling (>20 mm in diameter) were recorded between 2.1 and 3% in both groups. Fussiness preventing normal activities was the most frequently reported general symptom in both groups (1.6 and 1.9% in groups 1 and 2, resp.). Fever (rectal temperature >39.5°C) was reported in 0.4% (Group 1) and 0.3% (Group 2). All subjects included in the immunogenicity anal. had seroprotective or seropos. titers to the diphtheria, tetanus, hepatitis B and pertussis components of the vaccines. About 99 and 100% of infants had anti-PRP titers ≥0.15 mcg/mL in groups 1 and 2, resp. This study indicates that DTPa-HBV vaccine given in a single **injection** with a candidate Hib conjugate vaccine has a similar reactogenicity profile to that of two com. available vaccines (DTPa-HBV, Hib) given in two simultaneous **injections** to infants 2, 4 and 6 mo of age.
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AB The data provided by the Progetto Pertosse, a study on 15,601 children immunized with whole-cell or acellular diphtheria-tetanus-pertussis vaccines, or with a diphtheria-tetanus vaccine, allowed to gather detailed information on adverse reactions which can occur after the administration of the acellular vaccines used in Italy. Families of pertussis vaccinees should be informed in detail of expected adverse reactions. The results from Progetto Pertosse show that the reactogenicity of acellular vaccines is much lower than that observed with whole-cell vaccines, and similar to diphtheria-tetanus vaccines. The most common adverse events such as fever and local reactions start and end in most cases within 2 days of administration, and in the majority of cases have a short duration. The simultaneous administration of polio and hepatitis B vaccines does not increase the reactogenicity and does not affect the efficacy of acellular vaccines. **Injection** in the buttock is associated with a lower probability of observing common adverse reactions when compared to **injection** in the **thigh**. Children who experienced an adverse reaction are more likely to present the same event at following doses. Appropriate information to parents of vaccinees on the safety of acellular pertussis vaccines is necessary, it is useful to reassure the families of vaccinees and avoid interruptions of the **immunization** series due to false contraindications.